

# ROMEO Research Portal

## User Guide

Nova Scotia Health Authority  
Research Ethics Board

[Researcher Coordinator's User Manual](#)

# Accessing the Researcher's Portal

The Researcher's Portal is available through the Login at the following URL:  
<http://mreb.researchservicesoffice.com/Romeo.Researcher/Login.aspx>



If you are a first time user of the Researcher's Portal, you must click the 'register' button to create an account. Your username should be your primary email address. Once you have registered, you will receive an automatic email with instructions on setting up your password.

# Researcher's Home Page

You are now in the Researcher's Home Page! To access the REB application forms, click on "APPLY NEW"



*nova scotia  
health authority*

APPLY NEW News Useful Links Settings

Role : Principal Investigator	
Applications (Saved - Not Submitted)	(1)
Applications (Submitted - Requiring My Attention)	(0)
My Reminders	(0)
Applications (Submitted - Under Review) <a href="#">[Click here...]</a>	
Applications (Submitted - Post Review) <a href="#">[Click here...]</a>	
Applications (Withdrawn) <a href="#">[Click here...]</a>	

Role: Project Team Member	
Applications (Saved - Not Submitted)	(0)
Applications (Submitted - Requiring My Attention)	(0)
My Reminders	(0)
Applications (Submitted - Under Review) <a href="#">[Click here...]</a>	
Applications (Submitted - Post Review) <a href="#">[Click here...]</a>	
Applications (Withdrawn) <a href="#">[Click here...]</a>	

Researchers should visit the "Useful Links" section every now & then for helpful tips & hints

# Select the Proper Ethics Application Form (EAF)



APPLY NEW | News | Useful Links | Settings

## New Application Forms

All research projects being conducted in the Nova Scotia Health Authority (NSHA) and involving human participants, human biological materials (human embryos, fetuses, fetal tissue, reproductive materials, stem cells), NSHA patients, staff, resources or data are reviewed by the NSHA REB before the research begins. This applies to materials derived from living and deceased individuals.

Please read the descriptions below and select the appropriate ethics application form for your research submission.

## NSHA Ethics Staff

Application Name	Description	Status
INTERVENTIONAL STUDY - Ethics Application Form (EAF)	Interventional Study (or Clinical Trial): A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions. — clinicaltrials.gov If your study meets the requirements of an interventional study as per the definition above, complete this form. If your study does not meet the definition of an interventional study, complete the Ethics Application Form for Non-Interventional Studies.	Open
NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF)	Complete this form if your study is NOT a clinical trial. If your study is a clinical trial, complete the clinical trials EAF form.	Open

# Project Info Tab

Powered by **Process Pathways**

Welcome: Romeo Testing

**Application Ref No:** 1177

**Application Form:** NON-INTERVENTIONAL STUDY - Ethics Approval Submission (EAS) Form

**Save** **Close** **Print** **Export to Word** **Export to PDF** **Submit**

**\* Project Info** **Project Team Info** **\* NON-INTERVENTIONAL STUDY - Ethics Approval Submission (EAS) Form** **Attachments** **Approvals** **Logs** **Errors**

**Title \***:

Enter your study title exactly as it appears on your research protocol.

Note: The start & end dates are used for administrative and reporting purposes and will be entered by the MREB office staff.

**Start Date:**

**End Date:**

**Keywords:**

**Add**

**Clear all**

**IMPORTANT:** Please note that all fields preceded by \* are required. Failing to complete these fields will prevent the user from submitting the form.

# Project Team Info Tab

\* Project Info   **Project Team Info**   \* NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF)   Attachments   Approvals   Logs   Errors

**Principal Investigator**

Instructions : Do not hand type data for this section. The Principal Investigator (PI) section default populates with the researcher profile data for the project team member who creates are not the PI, click the Change PI button to search for and select an alternate researcher profile. If you load an alternate researcher profile to the PI section, be sure to reload your res the Other Project Team Info section below.

**Change PI**   **Refresh**

Prefix: Mr.   Last Name\*: Jenkins   First Name\*: Ken

Affiliation\*:

Project Team Info tab is automatically filled out with the logged in user's information

Rank: Research Staff

Gender: Male   Institution: QEII Health Sciences Centr

Phone1: 902 473 8126   Phone2:

# PI Role Versus Project Team Member Role

- ▶ At this point, the applicant (person completing application on behalf of the PI) will automatically be designated as PI on the application.
- ▶ The role of the applicant from PI to Project Team Member will need to be modified to ensure the application will follow the proper process. This can be done at any point during the completion of the form.
- ▶ As long as the applicant remains PI the application will continue to be accessible from the Researcher's home page under "Role: Principal Investigator".

My Files | APPLY NEW | News | Useful Links | Settings |

## Role : Principal Investigator

Applications (Saved - Not Submitted)	(1)
Applications (Submitted - Requiring My Attention)	(0)
My Reminders	(0)
Applications (Submitted - Under Review) [Click here...]	
Applications (Submitted - Post Review) [Click here...]	
Applications (Withdrawn) [Click here...]	

## Role: Project Team Member

Applications (Saved - Not Submitted)	(0)
Applications (Submitted - Requiring My Attention)	(0)
My Reminders	(0)
Applications (Submitted - Under Review) [Click here...]	
Applications (Submitted - Post Review) [Click here...]	
Applications (Withdrawn) [Click here...]	

# Project Team Info Tab

- Project Team Info tab is automatically filled out with applicant's info. To change the role of PI over to another researcher, click on "Change PI". **Important: DO NOT change PI's "Last Name" and "First Name" manually – always use "Change PI" feature.**

Application Ref No: 1181

Application Form: CLINICAL TRIAL - Ethics Approval Submission (EAS) Form

[Save](#) [Close](#) [Print](#) [Export to Word](#) [Export to PDF](#) [Submit](#)

[\\* Project Info](#) [Project Team Info](#) [\\* CLINICAL TRIAL - Ethics Approval Submission \(EAS\) Form](#) [Attachments](#) [Approvals](#) [Logs](#) [Errors](#)

## Principal Investigator

Instructions : Do not hand type data for this section. The Principal Investigator (PI) section default populates with the researcher profile data for the project team member who creates the file. If you are not the PI, click the Change PI button to search for and select an alternate researcher profile. If you load an alternate researcher profile to the PI section, be sure to reload your researcher profile to the Other Project Team Info section below.

 [Change PI](#) [Refresh](#)



Prefix:	<input type="text"/>	Last Name*:	<input type="text" value="Testing"/>	First Name*:	<input type="text" value="Romeo"/>
Affiliation*:					
<input type="text" value="District 9: Capital District Health Authority"/>					
Rank:	<input type="text"/>	Gender:	<input type="text" value="Unspecified"/>	Institution:	<input type="text" value="QEII Health Sciences Centre"/>

# Transferring PI Role to Another Researcher

Once you click “Change PI”, you can search the Investigator List for the name of the person to be assigned as PI. The list can be searched in a variety of ways, i.e. type the last name of the person in the “Last Name” field, or use the filter to select search criteria such as “Start With” or “Any part.”

**Investigator List**

**Close**

Instructions : Search for and select the researcher profile you want to load to this application file. If the project team member does not have a researcher profile, contact your system administrator for guidance.

Start With  Any part

Last Name:

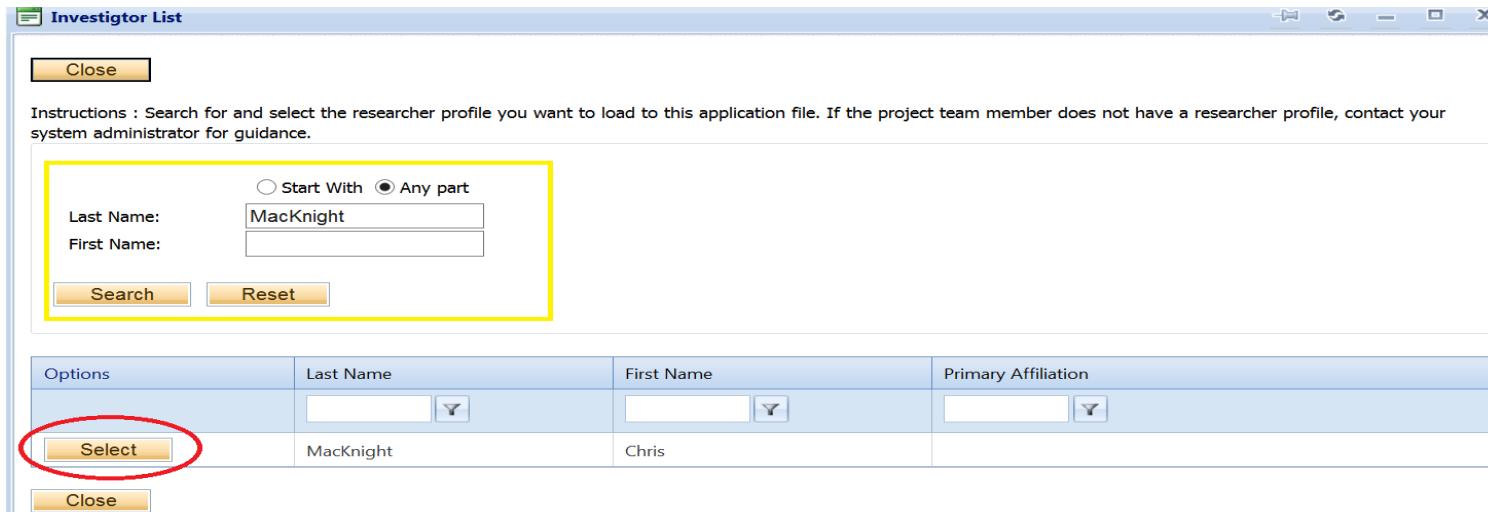
First Name:

**Search** **Reset**

Options	Last Name	First Name	Primary Affiliation
	Researcher <input type="text"/> <input type="button" value="X"/> <input type="button" value="Filter"/>	<input type="text"/> <input type="button" value="Filter"/>	<input type="text"/> <input type="button" value="Filter"/>

# Transferring PI Role to Another Researcher

- Once you've identified your PI – click on “select”.



The screenshot shows a Windows application window titled "Investigator List". The search interface at the top includes fields for "Last Name" (MacKnight) and "First Name", with radio buttons for "Start With" and "Any part". Below the search area is a table with columns: Options, Last Name, First Name, and Primary Affiliation. A single row is selected, showing "MacKnight" in the Last Name field and "Chris" in the First Name field. The "Select" button in this row is highlighted with a red oval. At the bottom of the window are "Search" and "Reset" buttons, and a "Close" button.

Options	Last Name	First Name	Primary Affiliation
<input type="button" value="Select"/>	MacKnight	Chris	

If you are unable to identify the person you are looking for from the investigators list, please email the system administrator ([mreb.notifications@nshealth.ca](mailto:mreb.notifications@nshealth.ca)). Your email should include the person's full name, title, business address, office phone number and email address. You will be notified as soon as the person has been added to the investigators list and will then be able to transfer the PI role over to them.

Project Team Info will automatically be updated with PI's information.

# Transferring P.I. Role to Another Researcher (cont'd)

At this point, you will also notice that the “Submit” button, previously located at the top of the form, has disappeared.

Important: the next step is to add yourself to the application as a team member. This must be done before you close the application. Failing to do so will result in you losing access to the application form once you exit the application form.

Powered by **Process Pathways**      Welcome: Romeo Testing

**Application Ref No:** 1181    **Project Title:**   
**Project Work Flow State:** Pre Submission

**Application Form:** CLINICAL TRIAL - Ethics Approval Submission (EAS) Form

Save    Close    Print    Export to Word    Export to PDF    **?** (circled)

\* Project Info    Project Team Info    \* CLINICAL TRIAL - Ethics Approval Submission (EAS) Form    Attachments    Approvals    Logs    Errors

**Principal Investigator**

Instructions : Do not hand type data for this section. The Principal Investigator (PI) section default populates with the researcher profile data for the project team member who creates the file. If you are not the PI, click the Change PI button to search for and select an alternate researcher profile. If you load an alternate researcher profile to the PI section, be sure to reload your researcher profile to the Other Project Team Info section below.

Change PI    Refresh

Prefix: Ms.    Last Name\*: Trenholm    First Name\*: Pamela

Affiliation\*: District 9: Capital District Health Authority

# Adding Team Members

- From the Project Team Info tab, scroll down to “Other Project Member Info” and click “Add New”
- Repeat the search process, this time assigning yourself to the team and selecting your role in the study from the drop down menu under “Role In Project” data field.
- You may add as many team members as required by clicking “Add New.”

**Other Project Member Info:**

Instructions : Do not hand type data for this section. To add more project team members to this application file, click the Add New button to search for and select from other researcher profiles.

Add New	Last Name	First Name	Role In Project

No records to display.

**Do not hand type data for this section. Always use “Search Profiles.”** If the person you are looking for is not in the list, please contact the system administrator (contact info on last page)

# PI Role versus Project Team Member Role

- Once the change has been made on the “Project Team Info” tab, the application will be accessible to the Research Coordinator and to the other team members from the Researcher’s Home Page under “Role: Project Team Member”.
- \*\*Important: The PI is the only person who can submit the application once it has been completed by the Research Coordinator.**

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APPLY NEW | News | Useful Links | Settings |

<b>Role : Principal Investigator</b>
Applications (Saved - Not Submitted) (0)
Applications (Submitted - Requiring My Attention) (0)
My Reminders (0)
Applications (Submitted - Under Review) <a href="#">[Click here...]</a>
Applications (Submitted - Post Review) <a href="#">[Click here...]</a>
Applications (Withdrawn) <a href="#">[Click here...]</a>

<b>Role: Project Team Member</b>
<u>Applications (Saved - Not Submitted)</u> (1)
Applications (Submitted - Requiring My Attention) (0)
My Reminders (0)
Applications (Submitted - Under Review) <a href="#">[Click here...]</a>
Applications (Submitted - Post Review) <a href="#">[Click here...]</a>
Applications (Withdrawn) <a href="#">[Click here...]</a>

# Ethics Application Form (EAF) (Interventional and Non-Interventional Studies)

The Ethics Form(s) have several sub-tabs all of which contain required questions. If you are unsure how to answer a question, try clicking on additional information may be available as seen in the screenshot below!

\* Project Info Project Team Info \* NON-INTERVENTIONAL STUDY - Ethics Approval Submission (EAS) Form Attachments Approvals Logs Errors

\* Principal Investigator Attestation \* Administrative Information \* Research Summary \* Research Protocol Information \* Compensation / Conflict of Interest \* Participant Identification and Informed Consent  
\* Privacy and Confidentiality \* Other Ethical Issues

**2.1)** \* Is this a locally-initiated investigator-driven research study (e.g. the PI is the study sponsor)?  
Principal investigators who serve as the sponsor of a drug or natural health product trial must meet all the obligations of the investigator and the sponsor as specified in ICH GCP E6 (sections 4 & 5) and the applicable Health Canada Regulations.

Yes, the PI is the study sponsor  
 No, the PI is not the study sponsor

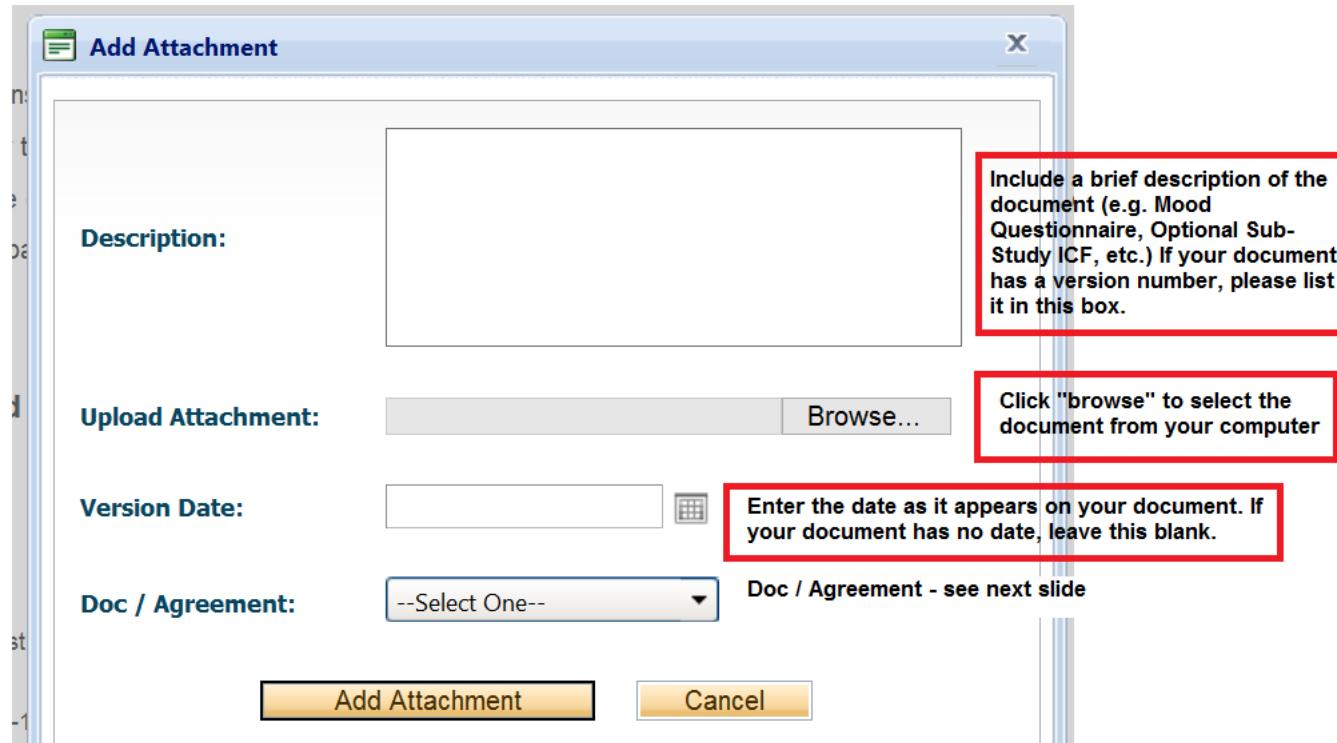
**2.2)** If not the PI, who is the study sponsor (state name of academic center/investigator, Industry, etc.)

**2.3)** \* Is the PI a trainee (e.g. student, resident, fellow)? A supervising investigator is required if the PI is a trainee and/or does not have a DHA/IWK affiliation.  
 Yes (A Supervising Investigator is required if the PI is a trainee and/or is not a staff member with a DHA/IWK appointment)  
 No (PI has a DHA/IWK affiliation)

Tip! ROMEO does not have an automatic save feature. Users are encouraged to hit the “Save” button after completing each tab.

# Attachments Tab

You should attach any relevant document(s) as listed on the “Attachments Tab.” Users may upload multiple attachments, provided that each is no larger than 5MB. Attachments may be word files, spreadsheets, jpeg files, pdfs, etc.



The screenshot shows a 'Add Attachment' dialog box with the following fields and instructions:

- Description:** A large text input field with a red callout box containing the text: "Include a brief description of the document (e.g. Mood Questionnaire, Optional Sub-Study ICF, etc.) If your document has a version number, please list it in this box."
- Upload Attachment:** A file input field with a "Browse..." button. A red callout box contains the text: "Click 'browse' to select the document from your computer"
- Version Date:** A date input field with a calendar icon. A red callout box contains the text: "Enter the date as it appears on your document. If your document has no date, leave this blank."
- Doc / Agreement:** A dropdown menu with the option "--Select One--". To the right, a red callout box contains the text: "Doc / Agreement - see next slide"

At the bottom are two buttons: "Add Attachment" and "Cancel".

# Attachments Tab (cont'd)

**Add Attachment**

**Description:**

**Upload Attachment:**

**Version Date:**

**Doc / Agreement:**

Click "add attachment" to complete the process

Budget Documents  
Certificate of Completion  
TCPS 2: CORE  
Consent Form and/or Addendum  
Current license to practice in NS  
Curriculum Vitae (CV)  
Data Collection Tool  
Health Canada Letter of Authorization / No

← →

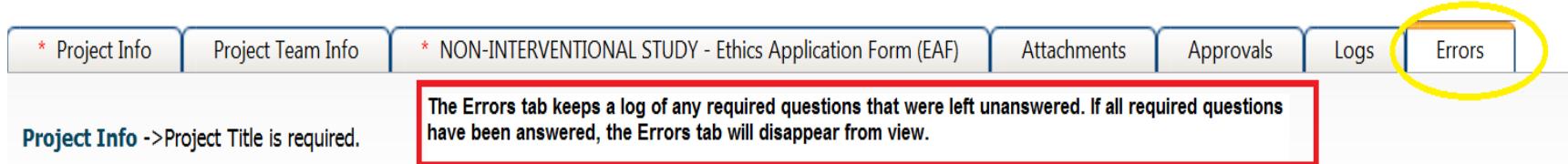
--Select One--

Browse...

Select the type of document from the drop down menu

Add Attachment Cancel

# Errors Tab



The Errors tab keeps a log of any required questions that were left unanswered. If all required questions have been answered, the Errors tab will disappear from view.

**Project Info** -> Project Title is required.

**NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF)** -> Administrative Information :2.1 Is this a locally-initiated investigator-driven research study (e.g. the PI is the study required.

**NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF)** -> Administrative Information :2.3 Is the PI a trainee (e.g. student, resident, fellow)? A supervising investigator is required. PI is a trainee and/or does not have a DHA/IWK affiliation.

**NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF)** -> Administrative Information :2.4 Has funding been obtained for this study? is required.

**NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF)** -> Administrative Information :2.7 What does this study involve? (select all that apply) is required.

**NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF)** -> Administrative Information :2.8 Has this study been reviewed by a committee, department, or division of a participating institution? is required.

**NON-INTERVENTIONAL STUDY - Ethics Application Form (EAF)** -> Administrative Information :2.9 Has this study been reviewed externally (e.g. by funding agencies or other academic institutions/organizations)? is required.

# Save and Continue...

At any point in the process, you may “Save and Close” the application and complete it at a later date. The information entered will be saved and can be accessed again through the Researcher’s home page under “Applications (Saved –Not Submitted)”. **Important: Do not close that application by clicking the X at the top of your browser, doing so will result in the application being “locked” preventing other team members from accessing it.**



APPLY NEW | News | Useful Links | Settings

Role : Principal Investigator	
Applications (Saved - Not Submitted)	(0)
Applications (Submitted - Requiring My Attention)	(0)
My Reminders	(0)
Applications (Submitted - Under Review) <a href="#">[Click here...]</a>	
Applications (Submitted - Post Review) <a href="#">[Click here...]</a>	
Applications (Withdrawn) <a href="#">[Click here...]</a>	

Role: Project Team Member	
Applications (Saved - Not Submitted)	(1)
Applications (Submitted - Requiring My Attention)	(0)
My Reminders	(0)
Applications (Submitted - Under Review) <a href="#">[Click here...]</a>	
Applications (Submitted - Post Review) <a href="#">[Click here...]</a>	
Applications (Withdrawn) <a href="#">[Click here...]</a>	

**ROMEO has no automatic save feature! But it does have a time out feature!** If you need to step away from your computer, always hit “Save and Close” as a precautionary measure. Failing to do so could result in information being lost or the application being “locked”. The user responsible for “locking” the application is able to “unlock” it by accessing it again and exiting properly. All other team members, who find themselves “locked out” of the application, can either contact the user who “locked” it or the system administrator for support (mreb.notifications@nshealth.ca)

# Submitting the Application

- ▶ From the moment you assign another PI and team members to the project, they will be able to view and edit the application.
- ▶ The PI is the only person who can submit the application, no other team member can do this on their behalf.
- ▶ The team member responsible for completing the application should notify the PI when the application is ready to be reviewed and submitted.
- ▶ Once the application has been submitted, the PI will receive an email confirming the receipt of the application – any team member associated with the application will be copied on the correspondence.

# Applications Under Review

Once the PI has submitted the application for review, you will receive an email confirming the receipt of the application – any team member associated with the application will be copied on the correspondence. At this stage, you will not be allowed to make any changes to the application. However, it is still available for viewing under “Applications (Submitted – Under Review)”.



APPLY NEW | News | Useful Links | Settings |

Role : Principal Investigator	
Applications (Saved - Not Submitted)	(0)
Applications (Submitted - Requiring My Attention)	(0)
My Reminders	(0)
Applications (Submitted - Under Review) <a href="#">[Click here...]</a>	
Applications (Submitted - Post Review) <a href="#">[Click here...]</a>	
Applications (Withdrawn) <a href="#">[Click here...]</a>	

Role: Project Team Member	
Applications (Saved - Not Submitted)	(1)
Applications (Submitted - Requiring My Attention)	(0)
My Reminders	(0)
Applications (Submitted - Under Review) <a href="#">[Click here...]</a>	
Applications (Submitted - Post Review) <a href="#">[Click here...]</a>	
Applications (Withdrawn) <a href="#">[Click here...]</a>	

# Work Flow State of Applications Under Review

Check the status of your application(s) under review under the “Work Flow State” column.

	File No	Project Title	Principal Investigator	Application Type	Status Snapshot	Workflow Message
	<input type="text"/> 	<input type="text"/> 	<input type="text"/> 	All	<input type="text"/> 	
 	100239	Test File	Romeo Testing (District 9: Capital District Health Authority)	CLINICAL TRIAL - Ethics Approval Submission (EAS) Form (Certification)Human Ethics	<b>Project Status:</b> Active <b>Workflow Status:</b> ORS Review	Test application being submitted for review [Acti... <i>[See more, inside under Logs section]</i>

# Applications Requiring Revisions

If the Board requires any revisions, the application will be pushed back to the researcher (applicant/PI). At this stage, you will be able to edit the application by clicking on this link: “Applications (Submitted – Requiring my Attention)”.

Remember that if you are making the revisions on behalf of the PI, you will need to let them know when the revisions are completed so that they may re-submit the application.



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## Role : Principal Investigator

Applications (Saved - Not Submitted) (0)

Applications (Submitted - Requiring My Attention) (0)

My Reminders (0)

Applications (Submitted - Under Review) [\[Click here...\]](#)

Applications (Submitted - Post Review) [\[Click here...\]](#)

Applications (Withdrawn) [\[Click here...\]](#)

## Role: Project Team Member

Applications (Saved - Not Submitted) (0)

Applications (Submitted - Requiring My Attention) (1)

My Reminders (0)

Applications (Submitted - Under Review) [\[Click here...\]](#)

Applications (Submitted - Post Review) [\[Click here...\]](#)

Applications (Withdrawn) [\[Click here...\]](#)

# Approved Applications

Once the application has been approved, the PI, Research Coordinator and Supervising Investigator (where applicable) will receive an automatic email the study has been approved. A formal approval letter in the form of email will also be sent. The application can no longer be modified but is available for viewing under “Applications (Submitted – Post Review)”



[APPLY NEW](#) | [News](#) | [Useful Links](#) | [Settings](#)

## Role : Principal Investigator

Applications (Saved - Not Submitted)	(0)
Applications (Submitted - Requiring My Attention)	(0)
My Reminders	(0)
Applications (Submitted - Under Review) <a href="#">[Click here...]</a>	
Applications (Submitted - Post Review) <a href="#">[Click here...]</a>	
Applications (Withdrawn) <a href="#">[Click here...]</a>	

## Role: Project Team Member

Applications (Saved - Not Submitted)	(0)
Applications (Submitted - Requiring My Attention)	(0)
My Reminders	(0)
Applications (Submitted - Under Review) <a href="#">[Click here...]</a>	
Applications (Submitted - Post Review) <a href="#">[Click here...]</a>	
Applications (Withdrawn) <a href="#">[Click here...]</a>	

# Logs Tab – Workflow Logs

- ▶ The Logs tab is a useful tool that shows the history of the application. Text in blue font represents most recent updates
- ▶ The “Workflow Logs” tracks and time stamps approvals and messages

Powered by Process Pathways

Welcome: Romeo Testing

File No: 100239 Project Title: Test File Project Work Flow State: ORS Review

Application Form: CLINICAL TRIAL - Ethics Approval Submission (EAS) Form

[Close](#) [Print](#) [Export to Word](#) [Export to PDF](#)

NOTE: You are in view only mode, and changes cannot be saved.

Project Info	Project Team Info	CLINICAL TRIAL - Ethics Approval Submission (EAS) Form	Attachments	Approvals	Logs
<input checked="" type="radio"/> Workflow Log <input type="radio"/> Project Log					
Timestamp	Activity Log	Workflow State	Workflow Message	User	Role/Group
10/07/2014 10:52	New File Submitted By Researcher Project Work Flow State has been changed from <a href="#">Pre Submission</a> to <a href="#">ORS Review</a>	<a href="#">Pre Submission -&gt; ORS Review</a>	Test application being submitted for review [Action: Submit]	Romeo Testing	Principal Investigator

# Logs Tab – Project Logs

- ▶ The “Project Logs” tracks and time stamps every action taken on the application.

File No: 100239 Project Title: Test File Project Work Flow State: ORS Review

Application Form: CLINICAL TRIAL - Ethics Approval Submission (EAS) Form

[Close](#) [Print](#) [Export to Word](#) [Export to PDF](#)

NOTE: You are in view only mode, and changes cannot be saved.

Project Info	Project Team Info	CLINICAL TRIAL - Ethics Approval Submission (EAS) Form	Attachments	Approvals	Logs
<input type="radio"/> Workflow Log	<input checked="" type="radio"/> Project Log				
<input type="radio"/> Workflow Log	<input checked="" type="radio"/> Project Log				
Timestamp	Log Activity				User
2014/07/10 11:09	Project Status has been changed from to <b>Active</b>				
2014/07/10 10:52	Project Work Flow State has been changed from <b>Pre Submission</b> to <b>ORS Review</b>				Romeo Testing
2014/07/10 10:45	<b>CLINICAL TRIAL - Ethics Approval Submission (EAS) Form :</b> Other Ethical Issues -> Are you aware of any other ethical issues regarding the design or conduct of the study? has been changed from " to <b>'No'</b>				Romeo Testing
	<b>CLINICAL TRIAL - Ethics Approval Submission (EAS) Form :</b> Privacy and Confidentiality -> Will researchers' personal information be transferred to parties who may store or access the information outside Canada? has been changed from " to <b>'No'</b> Privacy and Confidentiality -> Describe administrative, physical and technical measures to be taken to safeguard the personal health information and study data. has been changed from " to <b>'I'</b> Privacy and Confidentiality -> Will any personal health information (PHI) be collected or used to conduct the research or identify potential participants? (See description for definition) has been changed				

# Event Forms

- ▶ Event forms are: Amendments, Requests for Annual Approvals, Request for Acknowledgment, Serious Adverse Event (SAE) Reporting, Safety Updates and Study Completion.
- ▶ “Event Forms” allow researchers to make amendments to their approved ethics application(s).
- ▶ Event Forms can be accessed, completed and submitted by any member of the project team (i.e. the PI, Sub-investigator(s), Research Coordinator, etc.) as opposed to the original ethics application which can only be submitted and re-submitted by the PI.

# Accessing Event Forms

- ▶ You can access Event Forms at any time either under Role: Project Team Member by clicking on “Applications (Submitted – Post Review)”.
  - ▶ Applications will also be available within 30 days of the ethics renewal due date by clicking on “My Reminders”.



APPLY NEW | News | Useful Links | Settings |

**Role : Principal Investigator**

[Applications \(Saved - Not Submitted\) \(0\)](#)

[Applications \(Submitted - Requiring My Attention\) \(0\)](#)

[My Reminders \(0\)](#)

[Applications \(Submitted - Under Review\) \[Click here...\]](#)

[Applications \(Submitted - Post Review\) \[Click here...\]](#)

[Applications \(Withdrawn\) \[Click here...\]](#)

**Role: Project Team Member**

[Applications \(Saved - Not Submitted\) \(0\)](#)

[Applications \(Submitted - Requiring My Attention\) \(0\)](#)

[My Reminders \(0\)](#)

[Applications \(Submitted - Under Review\) \[Click here...\]](#)

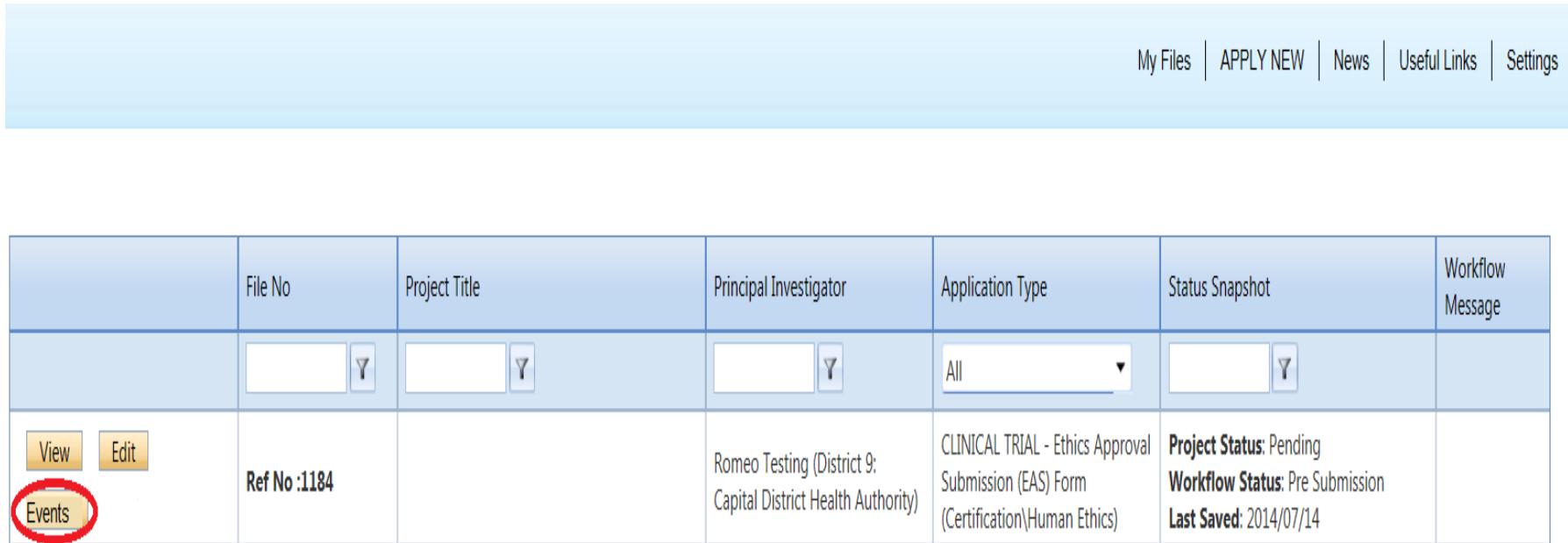
[Applications \(Submitted - Post Review\) \[Click here...\]](#) Available at any time

[Applications \(Withdrawn\) \[Click here...\]](#)

[My Reminders](#) Application available 30 days before the annual approval (renewal) form is due.

# Accessing Event Forms – Applications (Submitted – Post Review)

- By clicking on “Applications (Submitted – Post Review)”, you may view all of your approved ethics applications. From there, if you wish to submit an amendment form, a serious adverse event (SAE) or an annual approval (renewal) request, you can access the event forms by clicking on “Events”.



The screenshot shows a software interface with a navigation bar at the top containing links: My Files, APPLY NEW, News, Useful Links, and Settings. Below the navigation bar is a table with the following columns: File No, Project Title, Principal Investigator, Application Type, Status Snapshot, and Workflow Message. The first row of the table contains three empty text fields with a magnifying glass icon, a dropdown menu set to 'All', and an empty text field. The second row contains a row of buttons (View, Edit, Events) with the 'Events' button circled in red, a reference number 'Ref No:1184', the principal investigator 'Romeo Testing (District 9: Capital District Health Authority)', the application type 'CLINICAL TRIAL - Ethics Approval Submission (EAS) Form (Certification)\Human Ethics)', and status information: 'Project Status: Pending', 'Workflow Status: Pre Submission', and 'Last Saved: 2014/07/14'.

	File No	Project Title	Principal Investigator	Application Type	Status Snapshot	Workflow Message
	<input type="text"/> 	<input type="text"/> 	<input type="text"/> 	All	<input type="text"/> 	
  	Ref No:1184		Romeo Testing (District 9: Capital District Health Authority)	CLINICAL TRIAL - Ethics Approval Submission (EAS) Form (Certification)\Human Ethics)	<b>Project Status:</b> Pending <b>Workflow Status:</b> Pre Submission <b>Last Saved:</b> 2014/07/14	

# Accessing Event Forms

APPLY NEW | News | Useful Links | Settings |

File No: 6007658

Title: Test-January 17, 2013

## New Event Forms

[Study Closure](#)

[Request for Annual Renewal](#)

[Request for Amendment](#)

[Request for Acknowledgement](#)

[Safety related events reporting \(PSUR, DSMB, Safety ...\)](#)

[Major Study Violation](#)

[Local Serious Unexpected Adverse Reaction Reportin ...](#)

## My Reminders

### My Expired Reminders

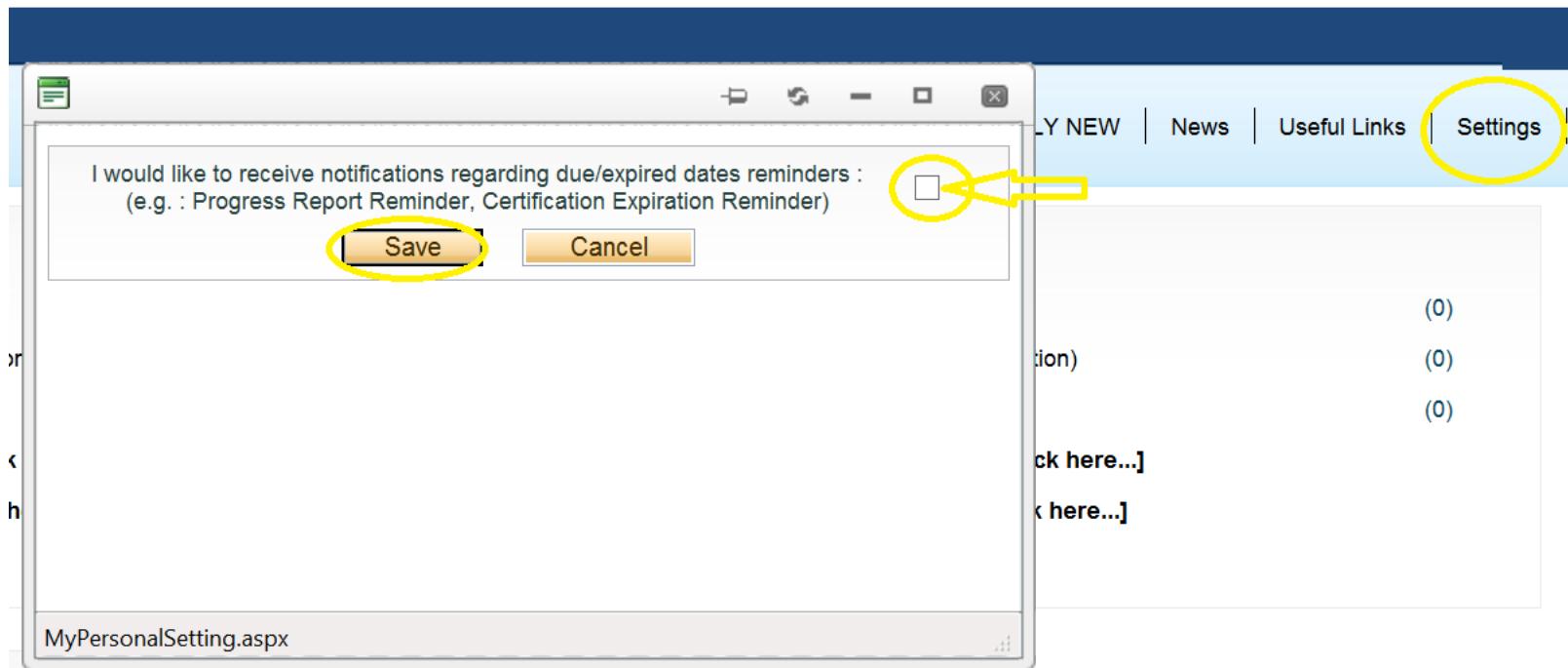
### My Events

	Form	Category	Status	SubmissionDate
<a href="#">View Event</a>	Y	Y	Y	Y

Select the form you need to submit by clicking on the hyperlinks under "New Event Forms".

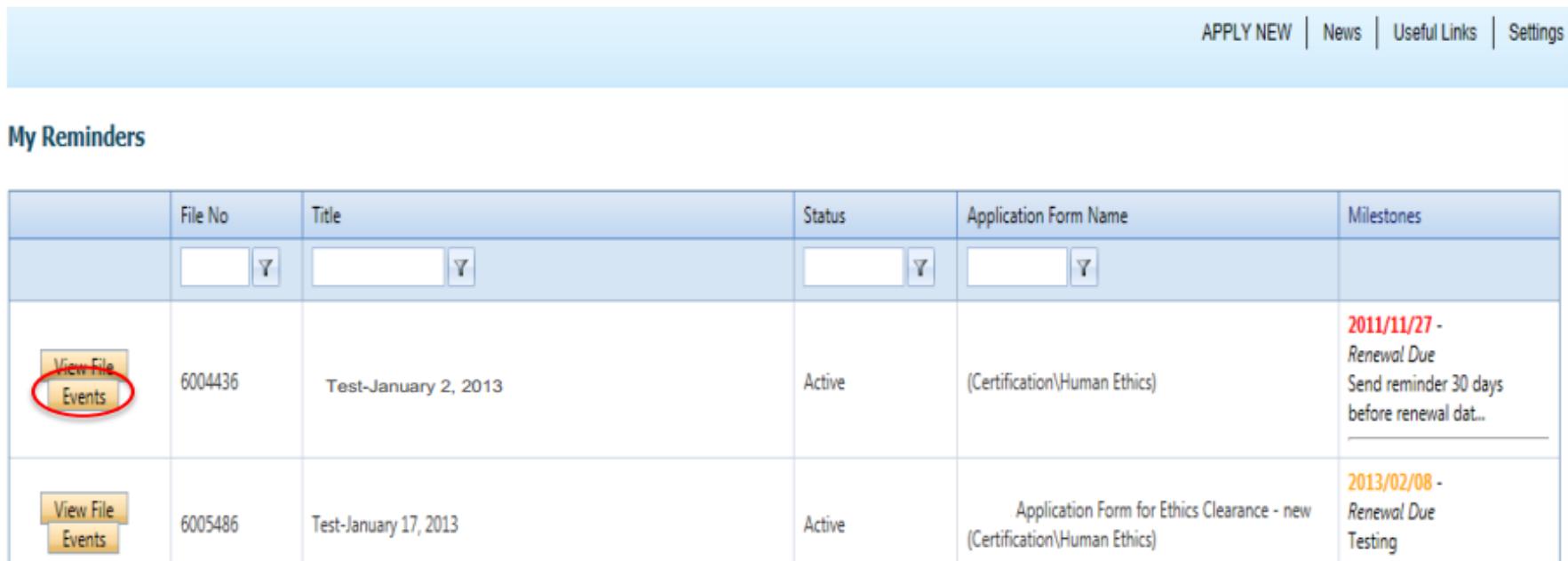
# Setting Reminders

- ▶ To receive reminders (e.g. annual approval due in 30 days), click on “Settings.” Tick the box to receive reminders and then click “save.”



# Accessing Event Forms – My Reminders

- From the “My Reminders” quick link you will see the due date of the “Milestones” –dates in yellow font are coming due, while dates in red font are past due. Click on “Events” to access the forms.



The screenshot shows a software interface with a light blue header bar containing the text "APPLY NEW | News | Useful Links | Settings". Below this is a section titled "My Reminders" with a table. The table has columns for "File No", "Title", "Status", "Application Form Name", and "Milestones". The "Events" button in the first row is circled in red. The data in the table is as follows:

	File No	Title	Status	Application Form Name	Milestones
 	6004436	Test-January 2, 2013	Active	(Certification\Human Ethics)	2011/11/27 - Renewal Due Send reminder 30 days before renewal dat...
 	6005486	Test-January 17, 2013	Active	Application Form for Ethics Clearance - new (Certification\Human Ethics)	2013/02/08 - Renewal Due Testing

# Event Info Tab

Save Close Print Export to Word Export to PDF Submit

Event Info \* Request for annual renewal Attachments Errors

Note(s)

Researchers and Research Coordinators are invited to add comments if they wish. For example, if a study is being reported as closed to recruitment, insert a note.

# Completing the Event Form

- ▶ Complete the form by answering all the questions of the Annual Renewal Form for All Studies (Interventional and Non-Interventional Studies). Once all of these questions have been answered, click on either the Interventional or Non-Interventional Studies sub-tab (as it applies to your study) and answer the remaining questions.

[Save](#) [Close](#) [Print](#) [Export to Word](#) [Export to PDF](#) [Submit](#)

Event Info Request for Annual Renewal Attachments

All Studies (Interventional & Non-Interventional studies) Interventional Study Non-Interventional Study

**Complete this form for ALL studies (Interventional & Non-Interventional Studies) IN ADDITION to either the Interventional OR the Non-Interventional request for annual renewal.**

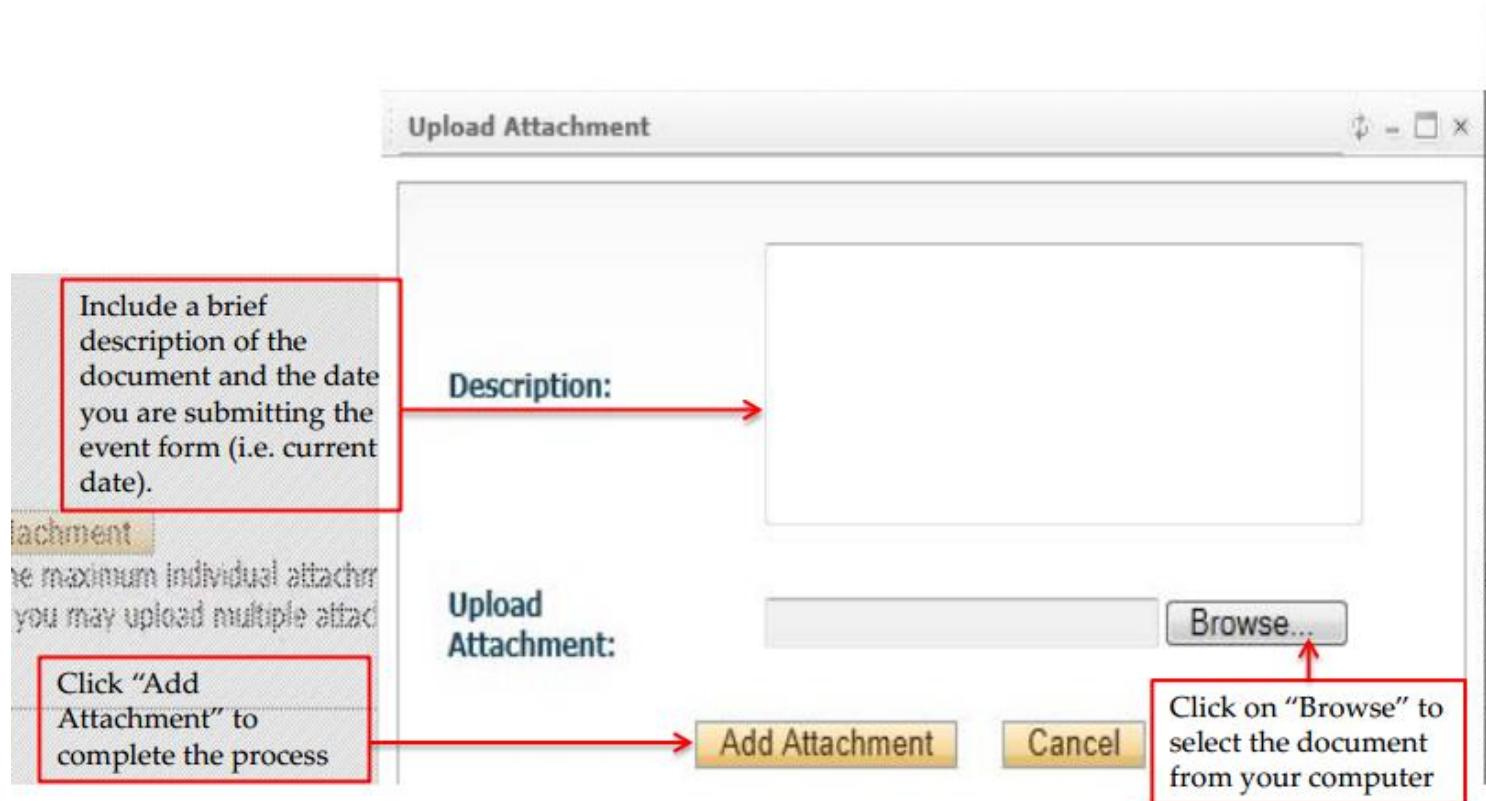
**i** 1.1 What is the status of the study (tick all that apply)?

Enrolling participants  
 Enrollment complete  
 Study procedures ongoing  
 Study has not yet started  
 Study procedures complete  
 Data analysis phase

Tip! Remember that ROMEO does not have an automatic save feature. Users are encouraged to hit the "Save" button after completing each tab.

# Attachments Tab

- Researchers are able to attach document(s) to the event form through the Attachments tab. Users may upload multiple attachments, provided that each is no larger than 5MB. Attachments may be Word documents, Excel spreadsheets, jpeg files, pdfs, etc.



# Errors Tab

Request for Amendment

[Save](#) [Close](#) [Print](#) [Export to Word](#) [Export to PDF](#) [Submit](#)

[Event Info](#) [\\* Request for Amendment](#) [Attachments](#) [Errors](#)

Request for Amendment -> Details of proposed amendment(s):1.13 Have you attached a copy of your revised team contact page clearly showing all changes by highlighting or underlining? is required.

The Errors tab keeps a log of any required questions that were left unanswered. If all required questions were answered, the Errors tab disappears.

# Submitting the Event Form

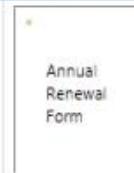
- ▶ Remember that any member of the project team (i.e. PI, Sub-Investigator, Research Coordinator, etc.) is able to submit event forms by simply clicking the "Submit" button at the top of the form.

Request for Amendment

The screenshot shows a software interface for a 'Request for Amendment' form. At the top, there is a horizontal bar with several buttons: 'Save', 'Close', 'Print', 'Export to Word', 'Export to PDF', and 'Submit'. The 'Submit' button is highlighted with a yellow circle. Below this bar, there is a navigation menu with tabs: 'Event Info', '\* Request for Amendment' (which is the active tab, highlighted in blue), 'Attachments', and 'Errors'. The 'Errors' tab is circled with a red circle and has a red arrow pointing to a callout box. The callout box contains the following text: 'Tip! Please note that incomplete applications will not submit successfully. If the "Errors" tab is still visible – as in this screen shot – then some of the required questions have been left unanswered and you will not be able to submit the application. Please check the "Errors" tab before hitting the submit button!' At the bottom of the form, there is a text area with the following content: 'Request for Amendment -> Details of proposed amendment(s): 1.13 Have you attached a copy of your revised team contact page clearly showing all changes by highlighting or underlining? is required.'

# Tracking the Event Form

- ▶ The PI and other members of the project team will not receive a confirmation email after submitting an event form.
- ▶ However, they can still track whether or not their form was submitted by accessing the application for which you submitted an event form – either through “Applications (Submitted – Post Review)” or “My Reminders” – and clicking on “Events”. Event forms that were started and saved, but not submitted will appear under “My Saved Events”.

My Reminders					
Milestone	Due Date	Comments	Sponsor	Event	Related Forms
Renewal Due	2013/02/8		N/A	Renewal	 Annual Renewal Form

## My Expired Reminders

Tip! As long as the event form has not been submitted, you will be able to edit it. If you can see the “Edit Event” button, you have not submitted the form yet!

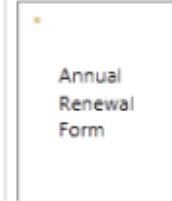
## My Saved Events

	Ref#	Comments	Category	Form
<a href="#">Delete</a> <a href="#">Edit Event</a>	32	Submitted on behalf of Research ...	Renewal	HSREB Annual Renewal Form for Approved Studies

# Tracking the Event Form (cont'd)

- Once the event form has been submitted, it will move down to "My Events". You will be able to view the event but will no longer be able to edit it.

## My Reminders

Milestone	Due Date	Comments	Sponsor	Event	Related Forms
Renewal Due	2013/02/08		N/A	Renewal	 Annual Renewal Form

## My Expired Reminders

Note that the "Status" of the application indicates: "Submitted by Researcher".

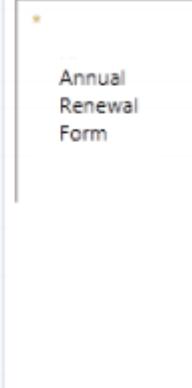
## My Events

	Form	Category	Status	SubmissionDate
<a href="#">View Event</a>	Annual Renewal Form	Renewal	Submitted by Researcher	2013/01/25

# Tracking the Event Form (cont'd)

- Once the event form has been assigned for review the “Status” of the application will change from “Submitted by Researcher” to “Pending”.

## My Reminders

Milestone	Due Date	Comments	Sponsor	Event	Related Forms
Renewal Due	2013/02/8		N/A	Renewal	 Annual Renewal Form

## My Expired Reminders

## My Events

	Form	Category	Status	SubmissionDate
<a href="#">View Event</a>	Annual Renewal Form	Renewal	Pending	2013/01/25

# Event Form Approval

- Once the event form has been reviewed and approved, the status of the event will change from “Pending” to “Active”.
- The PI , Research Coordinator and the Supervising Investigator (if applicable) will receive a confirmation email along with a copy of the formal approval letter. This letter has also been attached to the original application and can be viewed through the “Attachments” tab by any project team member.
- Please Note: The process for submitting any type of Event Form is the same as what has been described here.

## My Events

	Form	Category	Status	SubmissionDate
<a href="#">View Event</a>	Annual Renewal Form	Renewal	Active	2013/01/22

# Need assistance/have a question?

- ▶ Contact your system administrator
  - 902-473-2126
  - [mreb.notifications@nshealth.ca](mailto:mreb.notifications@nshealth.ca)

